DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94473d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 3000246860

December 19, 2003

Heng Nam Kin, President
HNK, Inc. dba Koha Oriental Foods
500 Alakawa Street, #104
Honolulu, Hawaii 96817

WARNING LETTER

Dear Mr. Kin:

On August 27 and 29, 2003, we inspected your seafood processing facility, located at 500 Alakawa Street, #104, Honolulu, Hawaii. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your Daegu (seasoned codfish/seasoned Pollack), Korean Style Seasoned Chirimen (Anchovy), and imported fishery products are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for the following products:

    a. Daegu (seasoned codfish/seasoned Pollack) to control the food safety hazard of pathogens; and

b. Korean Style Seasoned Chirimen (Anchovy) to control the food safety hazards of pathogens (including *Clostridium botulinum*) and histamines.

2. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However your firm does not have product specifications for any of the fish and fishery products that you import into the United States, including, but not limited to, the following products:

Product	**Country**	**Hazard(s)**
Canned Tuna	[redacted]	Pathogens, Histamine
Dried Anchovy		Pathogens, Histamine, ASP*
Dried Codfish		Pathogens, Parasites
Dried Pollack		Pathogens, Parasites
Dried Squid		Pathogens, Parasites
Frozen Fish Cakes		Pathogens
Frozen Fried Fish Cakes		Pathogens
Frozen Imitation Crab Meat Sticks		Pathogens
Frozen Oyster		Pathogens
Frozen Mackerel		Pathogens, Histamine
Frozen Salted Anchovy		Pathogens, Histamine, ASP*
Frozen Salted Mackerel		Pathogens, Histamine
Frozen Salted Cutlass		Pathogens
Frozen Breaded Shrimp		Pathogens, Undeclared sulfites
Frozen Breaded Hoki		Pathogens
Frozen Breaded Mackerel		Pathogens, Histamines
Seasoned Cod Gill		Pathogens, Parasites
Seasoned Cuttlefish		Pathogens
Seasoned Octopus		Pathogens, Parasites
Seasoned Pollack Entrails		Pathogens, Parasites
Seasoned Shad		Pathogens, Histamine

*Amnesic Shellfish Poisoning

3. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However,

a. Your firm did not perform an affirmative step for the following product-manufacturer combinations:

Product	Manufacturer and Country
Canned Tuna	[redacted]
Dried Anchovy	
Dried Anchovy	
Dried Codfish	
Dried Pollack	
Dried Pollack	
Dried Pollack	
Dried Pollack	
Dried Squid	
Frozen Fish Cakes	
Frozen Fried Fish Cake	
Frozen Fried Fish Cake	
Frozen Fried Fish Cake	
Frozen Fried Fish Cake	
Frozen Imitation Crab Meat Sticks	
Frozen Salted Anchovy	
Seasoned Cod Gill	
Seasoned Octopus	
Seasoned Pollack Entrail	
Seasoned Shad	
Seasoned Cuttlefish	

b. Your firm performed an affirmative step of obtaining a HACCP Compliance Certificate from the National Fisheries Products Quality Inspection Service, Ministry of Maritime Affairs and Fisheries, Republic of [redacted] for the following products:

- Frozen Salted Cutlass Fish, Chunk
- Frozen Salted Mackerel, Semi-Dressed
- Frozen Salted Mackerel, Fillet
- Frozen Pollack (Half-Dried), Semi-Dressed

manufactured by [redacted] that was not adequate. The certificate states that HACCP and sanitary programs were implemented in the production of the products in accordance with the Fisheries Products Quality Control Act. The certificate is not an adequate implementation of 21 CFR 123.12(a)(2)(ii)(B). Lot by lot certificates from foreign government inspection authorities must specifically declare that the seafood products were processed in accordance with the requirements of the FDA's seafood HACCP regulation [21 CFR 123].

c. Your firm performed an affirmative step of obtaining the HACCP plan for Saba Fillet processed by [redacted] that was not

adequate. The HACCP plan fails to identify the food safety hazard of histamine formation.

We also note that your "KOHO FOOD KOREAN STYLE SEASONED CHIRIMEN (MILD)" product is misbranded within the meaning of Section 403(i)(1) of the Act (21 USC 343(i)(1)) and 21 CFR 101.3(b) in that the product is not identified by its common or usual name in English as required by 21 CFR 101.15(c)(1).

At the conclusion of the inspection, the observed deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulation, and the Current Good Manufacturing Practice regulation (21 CFR 110).

We may take further action if you do not promptly correct these violations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. It has been four months since the completion of our inspection, which should have afforded you ample time to make corrections to the observations which were summarized on the Form FDA 483 issued to Mr. Hyong Sun Cho. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections.

Please send your reply to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosure:
Form FDA 483